Remarks

Claims 1-9, 11-22, and 25 are pending in this application. Claim 10 has been cancelled, and claims 23 and 24 have been previously canceled without prejudice or disclaimer. Claims 1, 11, 12 and 19 have been amended for the sole purpose of advancing prosecution.

Claim 1 has been amended to recite a "compliance monitor for a drug delivery device for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth." Support for this amendment appears throughout the specification and claims as originally filed, for example, the fifth full paragraph on page 5, of the present specification.

Claim 11 has been amended to recite the "compliance monitor according claim 1, further comprising a light sensor for sensing when the sensor is covered." Support for this amendment appears throughout the specification and claims as originally filed.

Claim 12 has been amended to recite the "compliance monitor according to claim 1, further comprising a conductivity sensor for sensing body conductivity." Support for this amendment appears throughout the specification and claims as originally filed.

Claim 19 has been amended to recite a "method of using a compliance monitor as defined in claim 1, to monitor use of a drug delivery device for administration of a drug, comprising the steps of: determining when a user operates the device to deliver a dose of the drug; sensing whether the device is properly positioned in contact with or relative to the user's body when the dose is delivered; and recording for each operation of the device whether or not the device was properly positioned." Support for this amendment appears throughout the specification and claims as originally filed.

Applicants, by cancelling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims cancelled herein or the original claim scope of any claim amended herein, in a continuing application.

No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. At pages 2-5 of the Official Action, claims 1-5, 7, 8, 10, 13-22 and 25 are rejected under 35 USC § 102(b) as being anticipated by Wolf (U.S. Patent No. 5,809,997).

The Examiner asserts that Wolf describe each and every element of presently pending claims 1-5, 7, 8, 10, 13-22 and 25.

In view of the following, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131.

The identical invention must be shown in as complete detail as is contained in the claim. R*ichardson v. Suzuki Motor Co.,* 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond,* 15 USPQ2d 1566 (Fed. Cir. 1990).

Claim 10 has been canceled without prejudice or disclaimer rendering this rejection of claim 10 moot.

As discussed above, amended claim 1 is directed to a compliance monitor for a drug delivery device for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

Amended claim 19 is directed to a method of using a compliance monitor as defined in claim 1, to monitor use of a drug delivery device for administration of a drug, comprising the steps of: determining when a user operates the device to deliver a dose of the drug; sensing whether the device is properly positioned in contact with or relative to the user's body when the dose is delivered; and recording for each operation of the device whether or not the device was properly positioned.

In contrast to the presently claimed subject matter, Wolf is directed to an electronic medication chronology device adapted for attachment to conventional

pressurized inhalant packages. *See* Wolf at the abstract. According to Wolf, a fast response thermistor is connected to the computing equipment and disposed between a hole in the side of the actuator housing and an opening in the chronology housing. *Id.*

The Examiner asserts that Wolf describes the use of a thermistor for sensing body temperature. Further, the Examiner asserts that the thermistor described in Wolf encompasses the temperature sensor of the presently claimed subject matter. Applicants respectfully submit that the "fast response temperature thermistor" described in Wolf, does not encompass the temperature sensor of the presently claimed subject matter. In particular, the "fast response temperature thermistor **425**" in Wolf is described as "being substantially in the path of inhalant flow within sensing chamber **510**." *See* Wolf at column 15, lines 37-39, and Figure 5. The temperature sensor of the presently claimed subject matter ***is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth***. Accordingly, the temperature sensor of the presently claimed subject matter determines body temperature directly. In contrast to the presently claimed subject matter, the thermistor described in Wolf determines body temperature only indirectly by detecting wave form characteristics. *See* Wolf at column 15, lines 63-66. Thus, Applicants submit that Wolf does not teach ***a compliance monitor for a drug delivery device for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein***

the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth, as presently claimed.

Accordingly, Applicants submit that Wolf does not teach each and every element of the presently pending claims, as required for anticipation under 35 USC § 102(b). Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-5, 7, 8, 13-22 and 25 under 35 USC § 102(b).

II. At pages 5-6 of the Official Action, claims 6 and 9 have been rejected under 35 USC § 103(a) as being unpatentable over Wolf in view of Reinhold et al. (US Patent No. 7,073,499).

The Examiner asserts that Wolf teaches all the elements of claims 6 and 9 except disclosing a compliance monitor wherein the drug delivery device is for topical administration of the drug. However, the Examiner alleges that it would have been obvious in view of Reinhold et al. to have modified the drug delivery device as described in Wolf to provide topical administration of a drug.

In view of the following, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or

present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *See KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 at 417-418. Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

It is submitted that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, neither Wolf nor Reinhold et al. teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

As discussed, claim 1 is directed to a compliance monitor for a drug delivery device for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was

properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

Claim 6 is directed to the compliance monitor according to claim 1, wherein the drug delivery device is for topical administration of the drug.

Claim 9 is directed to the compliance monitor according to claim 1, wherein the drug delivery device is selected from the group consisting of a dry powder inhaler, a pressurized metered dose inhaler and a nebulizer.

As discussed above, in contrast to the presently pending subject matter, Wolf does not teach or suggest a compliance monitor for a drug delivery device for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is ***a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth***, as recited in claim 1. Additionally, Applicants submit that Wolf does not teach or suggest that the drug delivery device is for topical administration, or that the drug delivery device is selected from the group consisting of a dry powder inhaler, a pressurized metered dose inhaler and a nebuliser, as presently claimed.

In contrast, Wolf only describes an electronic medication chronology device adapted for attachment to conventional pressurized inhalant packages employing a thermistor that only indirectly determines body temperature by detecting wave form characteristics. Accordingly, Applicants submit that Wolf fails to teach or suggest all the elements of the presently pending subject matter.

Reinhold et al. do not remedy the deficiencies of Wolf. Reinhold et al. merely describe generally that a respiratory delivery system, for example, an inhaler, could be used for topical or nasal delivery of gaseous substances. *See* Reinhold et al. at column 14, lines 58-63. Further, Reinhold et al. describe that respiratory delivery systems can be either metered dose inhalers, dry powder inhalers or nebulizers. *See* Reinhold et al. at column 1, lines 25-28. However, like Wolf, Reinhold et al. fail to teach or suggest a compliance monitor for a drug delivery device for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is ***a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth***, as recited in claim 1. Additionally, Applicants submit that, like Wolf, Reinhold et al. do not teach or suggest a temperature sensor that directly determines body temperature, as presently claimed. Accordingly, whether taken alone, or in combination, none of the cited

references teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

In view of the foregoing, it is submitted that, whether taken alone or in combination, Wolf and Reinhold et al. do not render the presently pending claims obvious within the meaning of 35 USC § 103(a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. At pages 6 and 7 of the Official Action, claims 11 and 12 have been rejected under 35 USC § 103(a) as being unpatentable over Wolf in view of Trueba (US Patent No. 6,684,880).

The Examiner asserts that it would have been obvious to modify the electronic medication chronology device described in Wolf to include a light sensor as described in Trueba. Further, the Examiner asserts that it would have been obvious to modify the device described in Wolf to include a conductivity sensor as described in Reinhold et al.

In view of the following, this rejection is respectfully traversed.

A brief outline of relevant authority is set forth above.

As discussed, independent claim 1 is directed to a compliance monitor for a drug delivery device for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is

mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

Amended claim 11 is directed to the compliance monitor according claim 1, further comprising a light sensor for sensing when the sensor is covered.

Amended claim 12 is directed to the compliance monitor according to claim 1, further comprising a conductivity sensor for sensing body conductivity.

Wolf is discussed in detail above. The full discussion of Wolf is incorporated herein by reference. As discussed, in contrast to the presently pending subject matter, Wolf does not teach or suggest a compliance monitor for a drug delivery device for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is ***a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth***, as recited in claim 1. Additionally, Applicants submit that Wolf does not teach or suggest a temperature sensor that directly determines body temperature, as presently claimed, as presently claimed. Accordingly, Applicants submit that Wolf does not teach or suggest every element of the presently claimed subject matter.

Applicants note that the Official Action on page 7 indicates that the Reinhold et al. reference is being used in this obviousness rejection, however, Trueba is the

reference indicated on page 6, paragraphs 6 and 7. For the purposes of advancing prosecution, Applicants submit, as discussed in Section II, that Reinhold et al. do not teach or suggest a temperature sensor that directly determines body temperature, as presently claimed. Accordingly, whether taken alone, or in combination, none of Wolf and Reinhold et al. teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

Trueba does not remedy the deficiencies of Wolf. Trueba merely describes the use of an optical sensor. *See* Trueba at column 13, lines 28-31. However, like Wolf, Trueba fail to teach or suggest a compliance monitor for a drug delivery device for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is ***a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth***, as recited in claim 1. Additionally, Applicants submit that, like Wolf, Trueba does not teach or suggest a temperature sensor that directly determines body temperature, as presently claimed. Accordingly, whether taken alone, or in combination, none of the cited references teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

In view of the foregoing, it is submitted that, whether taken alone or in combination, none of the cited references render the presently pending claims obvious

within the meaning of 35 USC § 103(a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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